

REMARKS

Claims 6 – 10, 12, 13, 16, 17 and 24 – 27 are pending.

New claims 28 and 29 are supported throughout the specification.

No new matter is added by this amendment.

- I. Claims 1, 12 and 13 are rejected under 35 USC 102(b) as being anticipated by Horwitz, US Patent No. 5,108,745 (the '745 patent).*

Applicants respectfully traverse this rejection.

The '745 patent discloses a method for producing a human vaccine against *Mycobacterium tuberculosis* in claims 13 – 17. There is no written description or enabling support for these claims in the specification of this patent. Rather, the entire teaching of this patent is on isolation of extracellular products of the intracellular parasite *Legionella pneumophila*. Therefore, solely by virtue of the fact that is non-enabling, this document should fail.

Further, the '745 patent does not teach or suggest *M. tuberculosis* antigens which are upregulated or expressed during the latent stage of a tuberculosis infection, much less the use thereof in a therapeutic vaccine.

In addition, the '745 patent does not teach or suggest any specific *Mycobacterium* antigens. The CFP10 antigen which is recited in claim 13 and mentioned by the examiner is not a latently expressed antigen; it is merely an optional further component of a vaccine of the invention.

For all of these reasons, reconsideration and withdrawal of the rejection is requested.

- II. Claims 6-10, 12, 13, 16, 17 and 24-26 have been rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement.*

Applicant respectfully traverses this rejection.

Applicants submit that it is common knowledge that the immunogenic properties of a peptide can be maintained with changes of the amino acid sequence. It is also

common knowledge for a person skilled in the art that the mechanism of an antigen used in a vaccine is due to specific epitopes within this antigen that are immunogenic, *e.g.* initiating a T-cell response. It is also easy for a person skilled in the art to find these fragments and analogues of a polypeptide which are immunogenic as illustrated in the example with Rv2031 (Ex.3), given the teachings of the present invention.

Reconsideration and withdrawal of this rejection is requested.

Please charge any deficiency in any fee to deposit account number 08-3040.

Respectfully Submitted,
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